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**From:** Segall, Martha [Segall.Martha@epa.gov]  
**Sent:** 7/20/2018 2:36:03 PM  
**To:** Hindin, David [Hindin.David@epa.gov]; Dombrowski, John [Dombrowski.John@epa.gov]  
**CC:** Vizard, Elizabeth [Vizard.Elizabeth@epa.gov]  
**Subject:** FW: Importance of the GLP Audit and Inspection Program...continued

**Ex. 5 Deliberative Process (DP)**

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Martha Segall  
Director (Acting)  
Monitoring, Assistance, and Media Programs Division  
Office of Compliance/OECA  
U.S. EPA  
ph: (202) 564-0723

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**From:** Messina, Edward  
**Sent:** Friday, July 20, 2018 10:22 AM  
**To:** Vizard, Elizabeth <Vizard.Elizabeth@epa.gov>; Segall, Martha <Segall.Martha@epa.gov>; Duffy, Rick <Duffy.Rick@epa.gov>  
**Subject:** FW: Importance of the GLP Audit and Inspection Program...continued

**Ex. 5 Deliberative Process (DP)**

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Ed Messina  
Acting Deputy Office Director (Programs)  
Office of Pesticide Programs  
U.S. EPA  
(703) 347-0209

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**From:** Jerry Baron [<mailto:jbaron@njaes.rutgers.edu>]  
**Sent:** Friday, July 20, 2018 9:47 AM  
**To:** Bodine, Susan <[bodine.susan@epa.gov](mailto:bodine.susan@epa.gov)>  
**Cc:** Keigwin, Richard <[Keigwin.Richard@epa.gov](mailto:Keigwin.Richard@epa.gov)>; Messina, Edward <[Messina.Edward@epa.gov](mailto:Messina.Edward@epa.gov)>; Ray McAllister <[rmcallister@croplifeamerica.org](mailto:rmcallister@croplifeamerica.org)>; Jay J. Vroom ([jvroom@croplifeamerica.org](mailto:jvroom@croplifeamerica.org)) <[jvroom@croplifeamerica.org](mailto:jvroom@croplifeamerica.org)>; Allison Jones <[allisonjones@naicc.org](mailto:allisonjones@naicc.org)>; Tammy White Barkalow <[tlwhite@njaes.rutgers.edu](mailto:tlwhite@njaes.rutgers.edu)>; Daniel Kunkel <[daniel.kunkel@rutgers.edu](mailto:daniel.kunkel@rutgers.edu)>; Sheryl Kunickis ([Sheryl.Kunickis@ARS.USDA.GOV](mailto:Sheryl.Kunickis@ARS.USDA.GOV)) <[Sheryl.Kunickis@ARS.USDA.GOV](mailto:Sheryl.Kunickis@ARS.USDA.GOV)>  
**Subject:** Importance of the GLP Audit and Inspection Program...continued

Ms. Susan Bodine  
Assistant Administrator, Office of Enforcement and Compliance Assistance  
U.S. Environmental Protection Agency  
Ariel Rios Building, 2201A  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460

Dear Ms. Bodine:

The IR-4 Project is a federally funded national research program whose mission is to facilitate the registration of conventional chemical pesticides and biopesticides for specialty crops (fruits, vegetables, herbs, nuts, etc.) and minor uses on major crops. We partner with the State Land-Grant Universities, USDA-Agriculture Research Service, and the crop protection industry to develop EPA required data to support the registration of crop protection products on crops that are often deemed “orphans” by industry. IR-4 is required to develop data following the same regulations and guidelines as private industry. Our ability to be successful in our mission is contingent on many elements, one of them is having competent Good Laboratory Practice (GLP) program.

Regular periodic GLP inspections of the regulated community by the EPA Office of Enforcement and Compliance Assurance (OECA) are an essential requirement for us to fulfill our mission domestically. The EPA inspections are becoming more critical as U.S. Specialty Crop farmers attempt to increase exports to take advantage of lucrative international markets. IR-4 is also involved numerous global projects with other publically funded data develop organizations. The data we generate domestically and in cooperative international projects must meet US GLP requirements but must also satisfy the requirements of the Organization for Economic Co-operation and Development (OECD) Mutual Acceptance of Data Decision (MADD) when that data is used to support export tolerances for our US growers.

The IR-4 Project supports the efforts of various members of the GLP regulated community to express the importance of the GLP monitoring program, the historical decline in its ability to fulfill its mission to properly monitor studies required by trading partners. We understand that there is some consideration of the movement of the FIFRA GLP monitoring to the Office of Chemical Safety and Pollution Prevention (OCSPP). We believe this move would be a positive step in light of some potential changes in fee for service funding and the logic of having this program in an area of the EPA that is already handling the administration of these funds.

We support the efforts of CropLife America and National Association of Independent Crop Consultants to elevate the GLP monitoring program to a position where it can fulfill its mission of providing adequate oversight of the US EPA’s GLP program. A robust GLP program in full compliance with the OECD MAD requirements demonstrates to all stakeholders the integrity of generated data that underpin pesticide registrations in the US and around the world. The EPA has a significant responsibility to vigorously defend its Pesticide Programs, and the GLP program should contribute in that regard.

Thank you for your consideration. If you have any questions or if I can be of assistance please feel free to reach out to me.

Sincerely yours,

Jerry J. Baron, Ph.D  
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